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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,389	10/22/2001	Gotz Nowak	VOS0003/US	1099

33072 7590 05/21/2004

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EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,389

Applicant(s)

NOWAK ET AL.

Examiner

Monique T. Cole

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cb 7

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-10 is/are rejected.
- 7) ☒ Claim(s) 4-7 and 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 4-7 and 11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3 & 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 & 8 are rendered indefinite because of their reference to "the surface" of claim

1. These claims recite that the surface is a microtiter plate, cuvette, measuring tube or stirring device. However, claim 1, on which both of these claims depend, refers to "the surface" as being the surface of the polymer. It is unclear whether Applicant intends for the polymer to be applied to the surface of the aforementioned substrates (i.e., microtiter plate, cuvette, measuring tube or stirring device) or whether it is Applicant's intention that the substrate is made of the polymer component.

For examination purposes, the Examiner is interpreting the language to mean that the surface of the polymer is applied to the recited substrates. Consequently, there is no antecedent basis for "the surface" in claims 3 & 8, and the claims should be redrafted to state, *"The process of claim 1 or 2, wherein said polymer surface is applied to the surface of a microtiter plate, etc."* Further clarification is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2 & 10 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,870,005 to Akiyoshi et al. (herein referred to as "Akiyoshi").

Akiyoshi teaches an analysis device/process comprising bringing a liquid bodily fluid sample (abstract) into contact with a multiplayer analysis element. The multiplayer analysis element comprises an antigen/antibody immobilized therein (col. 12, lines 36-51). The antigen/antibody may be labeled with fluorescein or a dye (col. 9, lines 9-20; col. 10, lines 19-22). The polymer employed in the multiplayer analysis element may be polymethyl methacrylate (col. 12, lines 5-8, 13). Once detection of the analyte is made, a change in fluorescent dye intensity is measured against a calibration chart to make a quantitative determination of the analyte concentration (col. 16, lines 4-32).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyoshi.

Akiyoshi differs from the instantly claimed invention in that it does not expressly teach that the multiplayer analysis element is applied to the surface of a microtiter plate, cuvette or measuring tube. However, it is conventionally known that polymeric gel substrates be applied to the surface of a plate, well or cuvette for the purpose of containing the sample and protecting the sample and the user from contamination. Thus, it would have been obvious to one having ordinary skill in the art to apply the multiplayer analysis element of Akiyoshi to a plate, cuvette or measuring tube given the art recognized benefits of sample containment and sample/user protection.

9. Claims 8 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyoshi as applied to claims 1, 2 & 10 above, and further in view of USP 5,017,342 to Haberzettl et al. (herein referred to as "Haberzettl").

Akiyoshi fails to teach that the polymer is applied to the surface of a stirring device that is introduced into the sample receptacle.

Haberzettl teaches an assay device which includes a support for use in determining the presence of biological substances in a sample under analysis, particularly antibodies and antigens, and particularly when that sample is a human body fluid (col. 1, lines 13-17). Haberzettl teaches that conventionally microtiter plates are used to assay physiological fluid for the presence of a target analyte. In preparing precoated microtiter plates, individual aliquots of the antibody are pipetted into each well to coat its bottom. Once in the lab, an aliquot of a sample under analysis is added to each well of the plate and then allowed to interact with the antibody. This conventional methodology has the problems of large margins of error due to non-uniformity of coating (col. 1, lines 23-46). Haberzettl instead teaches that an improved method & apparatus wherein a biological sample is added to the device which has been coated with antigen. If the antibodies are present in the sample, they will bind with the pre-coated antigen. Colorimetry is used to quantify the antibody (col. 3, lines 5-19). The stirring device may be made of polymethacrylate (col. 8, lines 17-20, 32-40).

Given the similar goals of Akiyoshi & Haberzettl (i.e., antigen-antibody assaying), it would have been obvious to one of ordinary skill in the art to consider the advantages of the Haberzettl method and apparatus, and modify the method and apparatus of Akiyoshi to be

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inclusive of a stirring element. Habertzettl clearly teaches that such a modification would be beneficial because it facilitates that accuracy and precision of the assay.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Monique T. Cole
Examiner
Art Unit 1743

MC/MC